

Biovigilance Component Hemovigilance Module Facility Enrollment or Component Activation





- Provide an overview of the National Healthcare Safety
 Network (NHSN) and the Hemovigilance Module
- Learn how to enroll in NHSN for facilities new to NHSN
- Learn how to activate the Biovigilance Component for facilities already enrolled in NHSN
- Understand location mapping in NHSN



- NHSN is a secure, Internet-based surveillance system managed by the CDC's Division of Healthcare Quality Promotion (DHQP)
- The Hemovigilance Module is designed for transfusion services staff in healthcare facilities to monitor recipient adverse reactions and quality control incidents related to blood transfusions



- Collect data from a sample of healthcare facilities to permit valid estimations of the:
 - Magnitude of adverse events
 - Adherence to practices to prevent adverse events
- Analyze and report collected data to permit recognition of trends
- Provide facilities with data that can be used for interfacility comparisons and local quality improvement activities

A comprehensive list of purposes can be found on the Web site:

http://www.cdc.gov/nhsn/



"The voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Section 304, 306, and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d))."



NHSN Structure

NHSN

Patient Safety Component Healthcare Personnel Safety Component

Biovigilance Component

> Hemovigilance Module



- The Hemovigilance Module requires surveillance from product receipt from suppliers to administration to patients
- The Hemovigilance Module captures:
 - Incidents related to the transfusion process
 - Errors and accidents that could lead to adverse reactions in transfusion recipients
 - Adverse transfusion reactions
 - Undesirable response or effect in a patient temporally associated with a transfusion
 - Denominators
 - Total number of units and/or aliquots of specified blood products transfused each month and samples collected for type and screen and/or crossmatch

Key Roles in NHSN

Facility Administrator

- The person enrolling the facility in NHSN
- Only person who can activate additional components for a facility
- Has add/edit/delete rights to facility data, users, and users' access
- Has authority to nominate/join groups for data sharing
- Only person who can reassign the role of Facility Administrator to another user

Component Primary Contact

- Someone who is familiar with the facility's transfusion services
- Interacts most closely with CDC for the component

Users

- Rights are determined by Facility Administrator: view data, data entry, data analysis
- May be given administrative rights
- One person may fill multiple roles



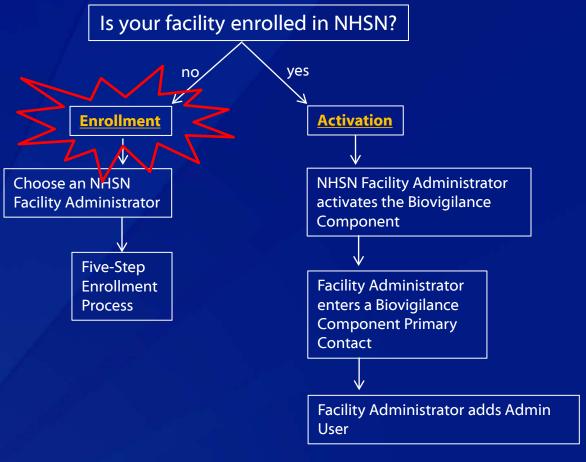
Enrolling in NHSN

- Facilities that are currently not participating in NHSN and wish to participate must <u>enroll</u> their facility in NHSN
 - Please visit http://www.cdc.gov/nhsn/enroll.html for more information regarding the enrollment process
- During the enrollment process, facilities may choose to participate in any of the NHSN components

Activating the Biovigilance Component

 Facilities that are <u>already enrolled</u> in NHSN and wish to participate in the Biovigilance Component must <u>activate</u> the component within NHSN

Getting Started in the Hemovigilance Module





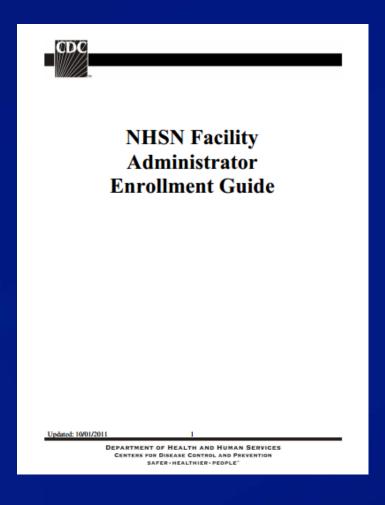
Email <u>nhsn@cdc.gov</u>





Enrollment of Facilities in NHSN

- Choose an NHSN Facility Administrator
 - This role should be filled by someone in the facility who has the authority to make decisions regarding facility and patient data
- Read the NHSN Facility
 Administrator Enrollment
 Guide
 - Available on the Web site at www.cdc.gov/nhsn
 - Please read this guide before enrollment





Five-Step Enrollment Process

1. Enrollment Preparation

2. Register

Receive 'Welcome to NHSN' email

3a. Request Digital Certificate

Receive 'NHSN Digital Certificate Request Confirmation' email

3b. Install Digital Certificate

Receive 'Action Required-Digital Certificate is Ready to Install' email

4. Submit Forms Electronically

Receive 'NHSN Facility Enrollment Submitted' email

5. Sign and Send Consent

Receive 'NHSN Enrollment Approved' email

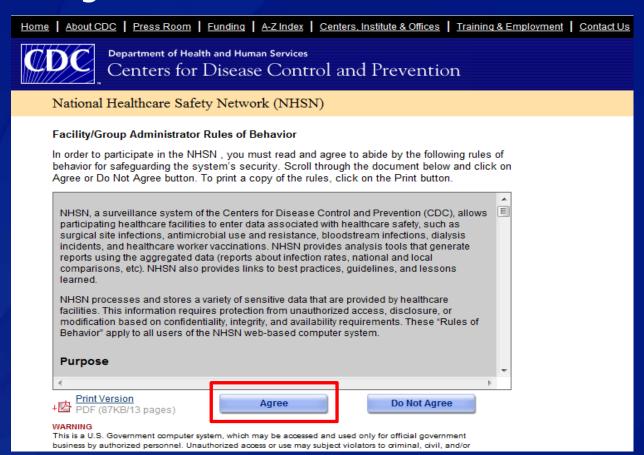


- Read the enrollment materials before beginning enrollment
 - "NHSN Facility Administrator Enrollment Guide"
 - "Purposes, Eligibility, Requirements and Confidentiality"
 - "NHSN Rules of Behavior for Facility/Group Administrators"
 - Enrollment materials can be found at http://www.cdc.gov/nhsn/library.html
- Review the Biovigilance Component-related training materials at http://www.cdc.gov/nhsn/bio.html
- Installing the digital certificate may require assistance from your IT department
 - Update spam-blockers to allow emails from nhsn@cdc.gov and PHINTech@cdc.gov
 - Add https://*.verisign.com to trusted sites and disable all pop-up blockers



Step 2 – Register

- ☐ Go to http://nhsn.cdc.gov/RegistrationForm/index.jsp
- Read and agree to the Rules of Behavior





Step 2 – Register

Personal Information

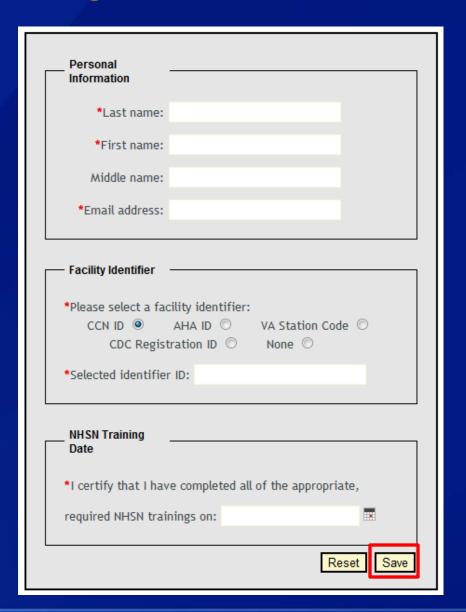
- This is the person who will be the NHSN Facility Administrator
- The email address must be the same for all steps of the process

Facility Identifier

Select <u>one</u> and enter the number

NHSN Training Date

 This is the date you completed all the required training



Response from CDC: Welcome to NHSN Email

Welcome! You are now registered in the National Healthcare Safety Network (NHSN).

In order to begin the NHSN enrollment process, you will need to obtain and install a digital certificate onto your computer.

Follow the instructions in the document "NHSN Facility Administrator Enrollment Guide" beginning at Step 3, to obtain and install the digital certificate so that you will be able to access the NHSN application through CDC's Secure Data Network (SDN). This document can be accessed at: http://www.cdc.gov/ncidod/dhqp/nhsn documents.html.

 Following successful registration, you will immediately receive a welcome to NHSN email with instructions to request a digital certificate



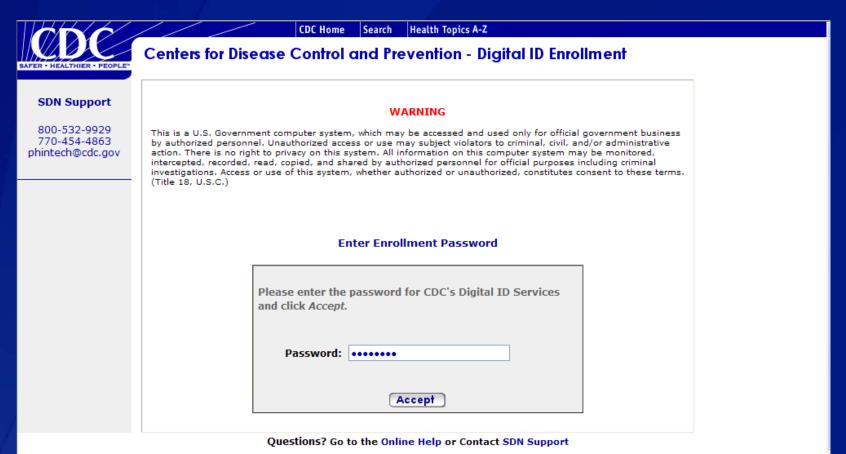
- Secure Data Network (SDN) provides secure online access to and exchange of information between CDC and public health partners
- Users enroll in SDN and obtain a digital certificate to gain access to CDC applications, including NHSN
- Digital Certificate
 - Electronic document installed on a user's computer
 - Allows for encrypted data transfer
 - Assures that the data have not been changed in transit
 - Certifies that the certificate owner transmitted the data
 - Renewed annually email is sent 30 days before expiration



Important Facts Digital Certificates and Email

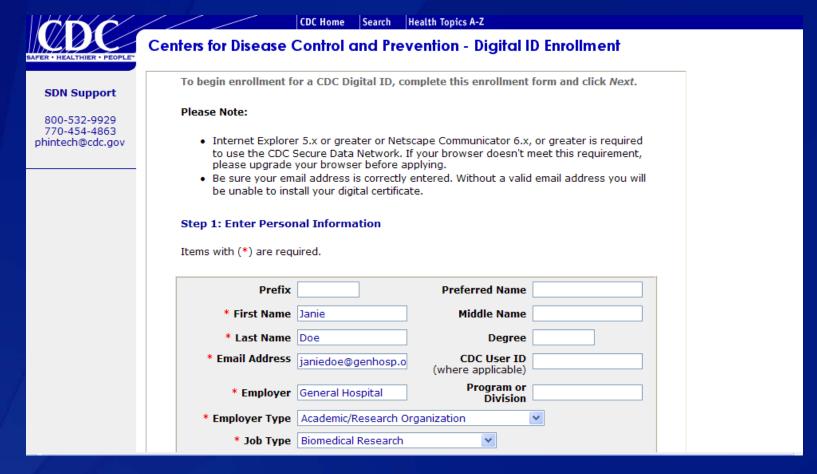
- A person cannot obtain a digital certificate without first being added as a user, with the exception of a Facility Administrator
- Every new user must obtain a digital certificate
- One digital certificate gives a user access to ALL facilities in which they are a user
 - i.e., one email address, one digital certificate
- Digital certificates can be installed on additional computers if necessary
- Multiple certificates can be installed on the same computer
- Most communication from CDC to users is by email
 - You <u>must</u> use the same email address throughout the NHSN enrollment or activation process as well as the application process for your digital certificate





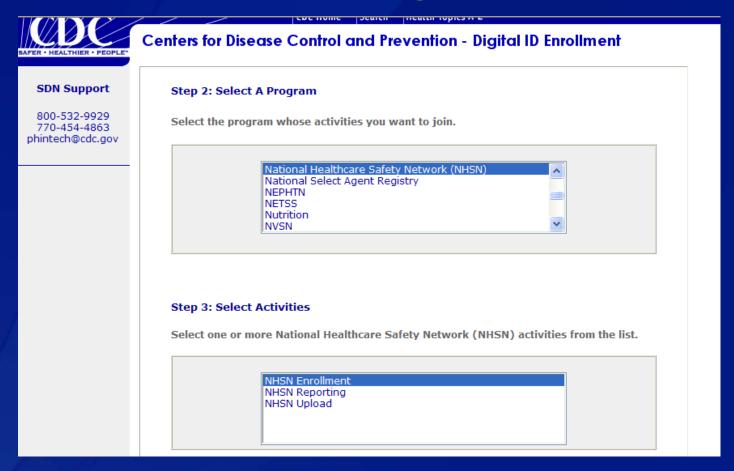
The Web site and password needed are provided to you in the email received upon completion of Step 2





NOTE: remember to use the email address you used during NHSN registration





- Select a Program Select National Healthcare Safety Network (NHSN)
- Select Activities Select only NHSN Enrollment





CDC Home | Search | Health Topics A-Z

Centers for Disease Control and Prevention - Digital ID Enrollment

SDN Support

800-532-9929 770-454-4863 phintech@cdc.gov

Step 4: Choose a Challenge Phrase

The challenge phrase is a password or phrase that you will need to provide every time you access the CDC Secure Data Network, and is also required to revoke your Digital ID.

For security reasons, a challenge phrase must:

- Be at least 8 characters long.
- Contain only English letters, numbers or any of these characters:



- Contain at least one non-alphabetic character.
- Not contain your name or any part of your email address.
- Not be a word, unless the word is either
 - Broken up by one or more non-alphabetic characters
 - Prefixed or suffixed by three or more non-alphabetic characters
- Not contain more than two consecutive repeating characters.
- Contain at least 4 unique characters.

Challenge phrases are case sensitive, so be sure to remember if any letters are capitalized. While not required, a challenge phrase containing mixed case letters is more secure, and we invite you to consider using one.

More Information and Examples.

Challenge Phrase

Carefully follow the instructions on the page and keep a copy of your challenge phrase for future reference



- Create your SDN challenge phrase (password)
- You will need to provide your challenge phrase (password) every time you access NHSN
 - Make a copy of your challenge phrase (password) for future reference
 - Note upper and lowercase letters and any special characters
- Enter and confirm your SDN challenge phrase (password), choose "Next"
- Do not share your challenge phrase, not even with IT



Response from CDC: NHSN Digital Certificate Request Confirmation Email

Once your challenge phrase (password) is created, you will receive confirmation that your digital certificate has been requested

From: NHSN (CDC)

Subject: NHSN Digital Certificate Request Confirmation

SDN has received your request for a digital certificate. Please do not apply for another digital certificate unless told to do so by someone from the SDN help desk. If you have not received an email from SDN within 5 working days informing you that you can download your digital certificate, or if you have trouble downloading your certificate, please contact SDN at 1-800-532-9929.

VERY IMPORTANT: To access the NHSN after you install your digital certificate, go to the SDN (https://sdn.cdc.gov), enter your challenge phrase, and then click on your NHSN activity.

If you have any problems with NHSN, please feel free to contact us.

Thank you!

National Healthcare Safety Network (NHSN) Support

Email: nhsn@cdc.gov



- Within 3 business days, you will receive an email from PHINTech with digital certificate installation instructions
 - Email subject line is "Action Required Your CDC Digital Certificate Is Ready to Install"
- The email contains instructions and installation links
 - We recommend that you contact your IT department to complete the installation process
- If you do not receive the email within 3 business days, contact SDN
 - Email: phintech@cdc.gov
 - Telephone: 1-800-532-9929

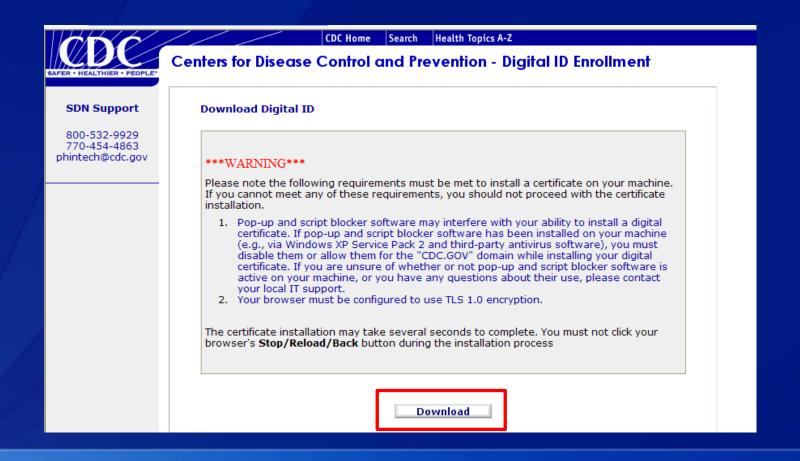


- Download the digital certificate onto the computer that you will use to access NHSN and report data
 - Click the link in the "digital certificate is ready to install" email
 - You may download your digital certificate onto multiple computers
- Carefully follow the instructions in the email for downloading the certificate
 - Recommend involving your IT department
- Must use Internet Explorer to download
- Enter your challenge phrase (password) & click "Submit"



Step 3b – Install Digital Certificate

Click "Download" to install digital certificate





Download begins automatically

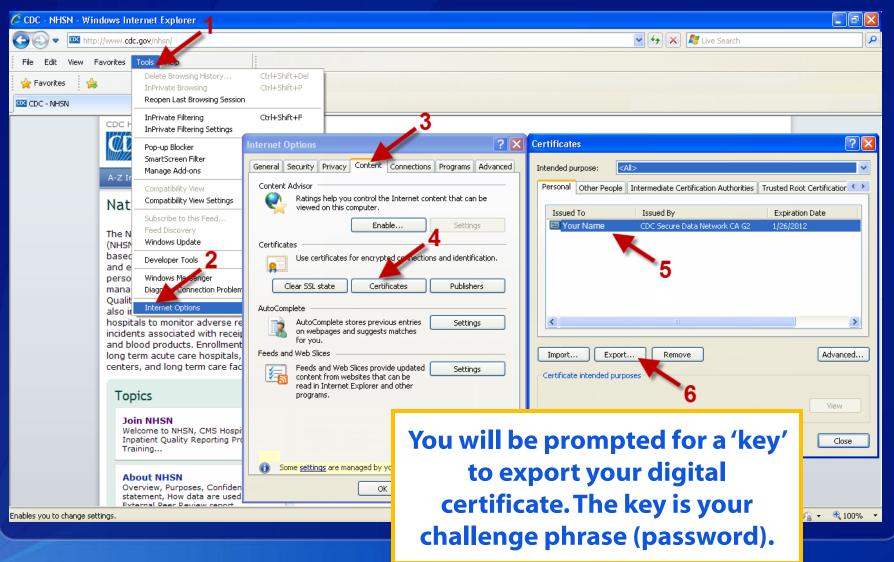
- If system settings are correct
- If settings are incorrect, contact your IT dept and/or SDN
- Security warning asks if you want to install and run VeriSign Import Control, click "Yes"

Once installed, confirmation certificate appears

- Verify installation in Internet Explorer
 - Click on "Tools" menu, choose "Internet Options"
 - Select the "Content" Tab, click "Certificates" button
- Save a copy of the digital certificate to an external device
 - Locate your certificate in Internet Explorer, click "Export" to save



Save a Copy of your Digital Certificate





Step 3b – Install Digital Certificate

If digital certificate is correctly installed, you will immediately be able to access https://sdn.cdc.gov/



If you cannot access SDN's Public Health Partners website, contact SDN at 1-800-532-9929



Step 4 – Submit Forms Electronically

Go to https://sdn.cdc.gov



Enter Challenge Phrase – Click "Submit"

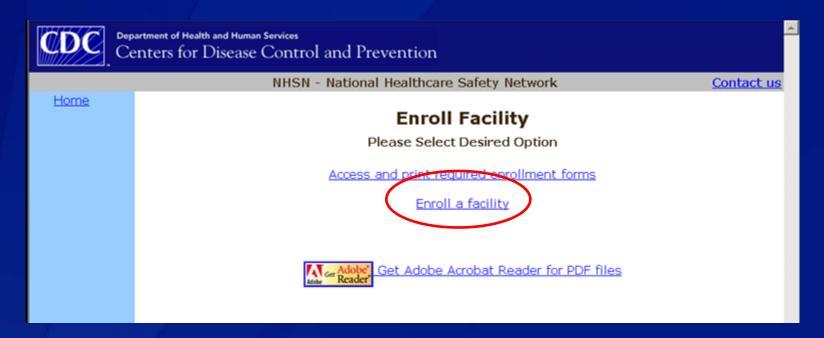


Under My applications – Click "NHSN Enrollment"





Step 4 – Submit Forms Electronically



- Click "Enroll a facility"
 - If you have not completed the required forms, print and fill out the forms before continuing the "Enroll a facility" step by selecting "Access and print required enrollment forms"
- The Annual Facility Survey must be completed online during the enrollment process



Step 4 – Submit Forms Electronically

 Once required forms are submitted, the confirmation message will display



Department of Health and Human Services
Centers for Disease Control and Prevention

NHSN - National Healthcare Safety Network

Contact us

Start Leave Enroll

Enroll Facility

☑ The enrollment for facility 'Test Facility' with tracking number 99999 has been completed. The Facility Administrator will receive an email with further instructions.

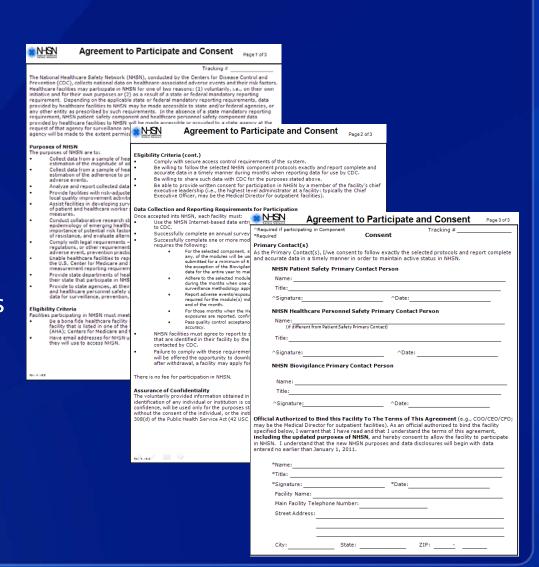


- The email will provide a link to access the "Agreement to Participate and Consent" form
 - You have 30 days to access the consent form
 - Consent form will open in a .pdf document
 - Once you have accessed the form, CDC must receive the signed form, by fax or email, within 60 days
 - If you do not receive this email, contact the NHSN user support at nhsn@cdc.gov



Step 5 – Sign and Send Consent

- Agreement to Participate and Consent includes:
 - NHSN Purposes
 - Eligibility Criteria
 - Data Collection and Reporting Requirements
 - Assurance of Confidentiality
 - Consent form





Primary Contacts for Activated Components

- Fill in the contact information for all activated components
- All signatures <u>must</u> be original

Official Authorization

- This section of the form must be completed by a C-level member of the facility (e.g., CEO, COO, CFO)
- The preferred method of returning the form is by fax
 - The fax number can be found at the bottom of page 3 of the form



Step 5 – Sign and Send Consent

- 2-3 business days after NHSN receives signed consent form, NHSN will activate your facility
- NHSN email notification of facility activation

From:

NHSN (CDC)

Subject:

NHSN enrollment approved

To: NHSN Facility Administrator

From: NHSN

Subject: NHSN enrollment approved

Your facility or group has been approved as a new member of NHSN. Welcome!

Facility Name: Test Facility

Facility ID #: XXXXX

As the Facility Administrator, you will now need to access the NHSN application through the SDN by selecting the NHSN Reporting activity. Once in the NHSN application, your first task should be to add those individuals who need to use the application ("users").

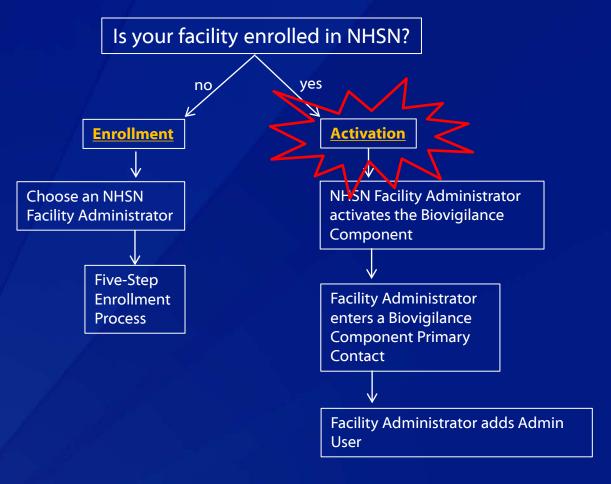
Once you add a user, that person will receive an email prompting her/him to obtain a digital certificate.

If you have any questions about NHSN, please contact us at nhsn@cdc.gov or http://www.cdc.gov/nhsn.



- After enrollment is completed the Facility Administrator can:
 - Add users and assign user rights
 - Map facility locations
 - Join Groups and share data
- Once the Annual Facility Survey has been completed, the facility can enter Monthly Reporting Plans and begin reporting data to NHSN





- Are you not unsure of your facility's status with NHSN?
 - Email <u>nhsn@cdc.gov</u>





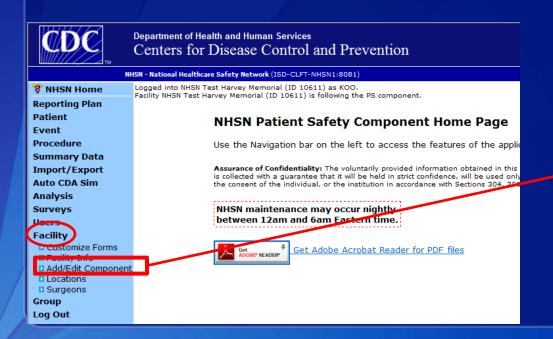
Activating Biovigilance Component for Existing NHSN Facilities

- Only the NHSN Facility Administrator can activate a new component
 - The Facility Administrator will designate a Primary Contact for the Biovigilance Component, i.e. someone who is familiar with the facility's transfusion services
- Add the Primary Contact as a user and give them
 Administrative rights to the Biovigilance Component
 - Being added as the Primary Contact for a component <u>does not</u> automatically add that person as a user
 - This user with Administrative rights will be able to add additional Biovigilance users and share data using the Group function for the Biovigilance Component



Activating the Biovigilance Component

- □ Facility Administrator logs into https://sdn.cdc.gov
 - Under 'My Applications' select NHSN Reporting
 - Log into any active component
- From the Home Page, click "Facility" then "Add/Edit Component"
- Facility Administrator enters a Biovigilance Primary Contact, adds them as a user, and gives them Administrative user rights



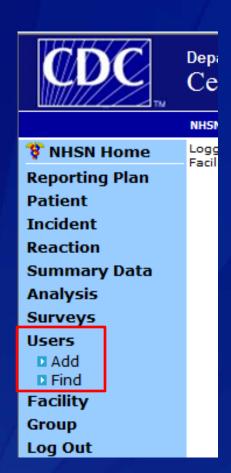




After the Facility Administrator adds the Biovigilance Component, the following must be completed:

- 1. Hemovigilance Module Annual Facility Survey
 - The survey does not have to be completed at activation, but must be completed before data entry
 - http://www.cdc.gov/nhsn/forms/biovigilance_forms.html
- 2. Mapping locations
 - Confer with other component Primary Contacts before making changes to locations in NHSN
- 3. Hemovigilance Module Monthly Reporting Plans
 - Must be completed for each month surveillance is conducted





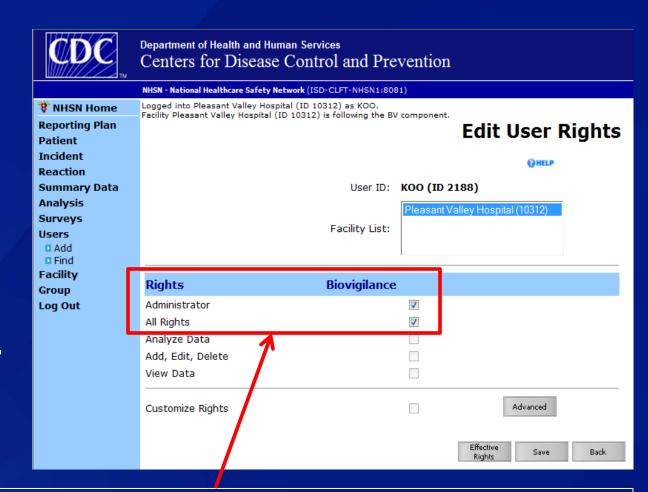
Adding Users

- To add users to your facility, click "Users" on the navigation bar, then click "Add"
- "Add User" screen mandatory fields
 - User ID created by the facility
 - First Name
 - Last Name
 - Email Address Must be an active/correct address for the user
- Any user with administrative rights can add users

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User Rights

- After saving the new user information, the "Edit User Rights" screen will appear
- Please be sure to confer the proper rights to users



The person assigned as the Primary Contact must be given rights as Administrator



- Facility locations are used to stratify data in NHSN
- Facility location information is shared across components
 - Locations used in one component may be used in other components and should not be duplicated or deleted
 - Confer with other component Primary Contacts before making changes to locations in NHSN

Location Mapping in NHSN

- Locations are defined as physical areas of a facility
 - For the Biovigilance Component, locations are defined as any area where patients are transfused, could experience adverse reactions, and/or where products may be handled
- Facility locations must be "mapped" to a standard CDC location code
 - A list of CDC location codes, labels and descriptions can be found on the NHSN Web site under the Resource Library, NHSN Codes and Variables
 - http://www.cdc.gov/nhsn/library.html



Congratulations!



Questions or Need Help? Contact user support



